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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,725

03/14/2005

Robert W. Shaw

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(TXTECH-0001)

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25555 7590 02/08/2008  
JACKSON WALKER LLP  
901 MAIN STREET  
SUITE 6000  
DALLAS, TX 75202-3797

EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

02/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/527,725

Applicant(s)

SHAW ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-41 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/28/05 &amp; 5/26/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Applicants are advised that their petition to revive the application from abandonment, received on October 17, 2007 has been Granted.

#### *Election/Restrictions*

Applicant's election without traverse of Group III, consisting of claims 42-46, in the reply filed on April 4, 2007 is acknowledged.

Claims 1-41 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on April 4, 2007.

#### *Information Disclosure Statement*

The IDS's received on April 28, 2005 and May 26, 2005 are acknowledged.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is indefinite for reciting the phrase, "composition...comprising a nucleic acid ligand with SEQID# 5," because it is unclear whether the composition comprises a nucleic acid ligand having (i.e., with) the sequence depicted with SEQ ID Number 5; or the composition comprises a nucleic acid ligand bound to (i.e., with) the sequence SEQ ID Number 5.

For the purpose of prosecution, the former interpretation is assumed.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-45 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising SEQ ID Number 5 which inhibits *B. cereus* 5/B/6 metallo- $\beta$ -lactamase, does not reasonably provide enablement for a genus of lactamases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The present rejection is based on recitation of the activity of the nucleic acid ligand (i.e., a particular inhibition) made in the claims.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in *In Re Wands* (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

The Nature of the Invention:

The present invention is drawn to an unpredictable art of producing an inhibiting nucleic acid ligand for a particular substrate (i.e., lactamase) by SELEX.

Breadth of Claims:

Claims as currently recited, is drawn to a composition comprising SEQ ID Number 5, which is capable of inhibiting the activity of a genus of lactamases, or subgenus of class B lactamase, and metallo- $\beta$ -lactamases, for which the present specification does not justify such a breadth.

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Amount of Guidance & Working Examples:

The present specification states that a 30-mer, derived by SELEX method was capable of inhibiting the activity of a particular type of species of lactamase, that is *B. cereus* 5/B/6 metallo- $\beta$ -lactamase (page 11, section [0036] and [0080]).

According to the specification, this 30-mer of completely rand sequence not only bound tightly and specifically to *B. cereus* 5/B/6 metallo- $\beta$ -lactamase, but also was able to inhibit the enzyme (page 22, section [0081]; page 31, sections [0112] and [0113]).

The specification, when testing for its (30-mer) specificity in inhibition found that said 30-mer was incapable of inhibiting the activity of other type of lactamase, such as *B. cereus* 569/H/9  $\beta$ -lactamase (page 31, section [0116]).

The specification also discloses that two different structures of the aptamer (the 30-mer) were predicted using MFold program, both of which contained SEQ ID Number 5 (page 35, sections [0137] and [0138]), resulting in the hypothesis that said SEQ ID, “may be important for interaction with metallo- $\beta$ -lactamase” (page 35, section [0138]).

This sequence was synthesized and tested for its binding and inhibition ability against a particular species of lactamase, *B. cereus* 5/B/6 metallo- $\beta$ -lactamase (page 36), but produced *no inhibition affect on the activity of other type of lactamase, namely B. cereus 5/B/6 metallo- $\beta$ -lactamase.* (see page 36, section [0143]).

Unpredictability of the art:

A method of SELEX for arriving at an aptamer which inhibits a particular substrate remains completely unpredictable, requiring empirical determination for every molecule being tested.

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Therefore, for the above reasons, one of skill in the art would not be capable of practicing the invention fully commensurate in scope of the claims without undue experimentation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Stjernschantz et al. (WO 99/02165, published January 21, 1999).

Stjernschantz et al. disclose an oligonucleotide 20-mer (EP<sub>2</sub> primary primer) which comprises a 100% homology to that of the instant SEQ ID Number 5 as evidenced below.

Query Match	100.0%;	Score 10;	DB 2;	Length 20;
Best Local Similarity	100.0%;	Pred. No. 2.8e+04;		
Matches	10;	Conservative	0;	Mismatches 0; Indels 0; Gaps 0;
1y	1	CCAAACTTGG	10	
2b	8	CCAAACTTGG	17	

As the 20-mer disclosed by Stjernschantz et al. comprises the critical region which is responsible for binding and inhibiting *B. cereus* 5/B/6 metallo- $\beta$ -lactamase, it is asserted that the oligonucleotide of Stjernschantz et al. would necessarily have the same inhibition activity.

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Therefore, the invention as claimed is anticipated by Stjernschantz et al.

### ***Conclusion***

No claims are allowed.

### ***Inquiries***

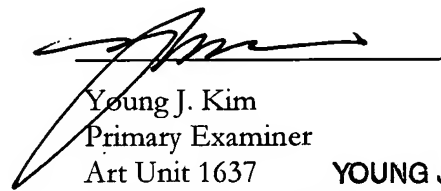
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Young J. Kim  
Primary Examiner  
Art Unit 1637  
1/24/2008

**YOUNG J. KIM  
PRIMARY EXAMINER**

YJK